

UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF MASSACHUSETTS

United States of America
ex rel. Jeffrey J. Bierman,

Plaintiff,

v.

Orthofix International N.V., et al.,

Defendants.

Civil Action No. 05-10557 (EFH)

United States of America
ex rel. Marcus Laughlin,

Plaintiff,

v.

Orthofix International, NV, et al.

Defendant.

(formerly Civil Action No. 1:08-cv-11336
(JLT))

**ORTHOFIX INTERNATIONAL N.V.’S AND ORTHOFIX, INC.’S DEFENDANT-
SPECIFIC MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO
DISMISS RELATOR BIERMAN’S SECOND AMENDED AND SUPPLEMENTAL
COMPLAINT WITH PREJUDICE**

Defendants Orthofix International N.V. and Orthofix, Inc. (“the Orthofix Defendants”¹) respectfully submit this defendant-specific memorandum of law in support of their Motion to Dismiss Relator Jeffrey J. Bierman’s Second Amended and Supplemental Complaint with Prejudice. The Joint Memorandum in Support of Defendants’ Motions to Dismiss the Second Amended and Supplemental Complaint of Relator Jeffrey J. Bierman (“Joint Memorandum”)

¹ The two Defendant entities are in fact independent and distinct—as Relator Bierman recognizes, it is Orthofix, Inc., not Orthofix International N.V., that “manufactures, markets, distributes and directly bills Medicare for the Spinal Stim, Physio-Stim and Cervical Stim osteogenesis stimulators” at issue in this action. (SAC ¶ 16).

explains why Bierman's Second Amended and Supplemental Complaint (the "SAC") fails to state claims against any Defendant under Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure. This memorandum is submitted on behalf of only the Orthofix Defendants, and applies the principles explained in the Joint Memorandum to show that the SAC falls far short of pleading Bierman's False Claims Act ("FCA") and state false claims act claims against either Orthofix, Inc. or Orthofix International N.V. with the specificity required by Rule 9(b). Indeed, the SAC's Orthofix-Defendant-specific allegations—based almost entirely on second-hand information and on unremarkable, publicly available descriptions of Orthofix, Inc.'s business practices—fail to identify any relevant details of false claims submitted by Orthofix, Inc. and fail to allege any claims submitted by Orthofix International N.V. at all, nor any fraudulent conduct engaged in by either Orthofix Defendant. This failing, despite four opportunities to craft an adequate pleading, demonstrates that the SAC should be dismissed with prejudice.²

ARGUMENT

I. BIERMAN'S SAC DOES NOT IDENTIFY ANY INVOLVEMENT BY EITHER ORTHOFIX DEFENDANT IN THE SUBMISSION OF FALSE CLAIMS OR IN FRAUDULENT CONDUCT WITH SUFFICIENT PARTICULARITY TO SATISFY RULE 9(B)

Bierman's SAC does not describe with particularity any specific false claims submitted by Orthofix, Inc., or any details of any false or fraudulent representation made to get claims paid. It does not allege a single false claim submitted by Orthofix International N.V., or that Orthofix International N.V. even submits claims to any payer.³ Nor does it allege sufficient time, manner, and place details of any fraudulent conduct by either Orthofix Defendant, or offer any connection between any alleged fraudulent conduct and any specific claims submitted to the government. In

² For procedural and other background information, please refer to the Joint Memorandum.

³ The only paragraphs in the SAC that refer specifically to Orthofix International N.V. at all merely provide basic background information. (See SAC ¶¶ 15–16.)

fact, the SAC alleges entire theories of liability against the Orthofix Defendants based on conclusory statements of “information and belief,” and supplies only a few scattered and unconnected facts purporting to justify those beliefs. Accordingly, the allegations against the Orthofix Defendants should be dismissed for failing to comply with Rule 9(b).

As explained in greater detail in the Joint Memorandum, “Rule 9(b) requires the pleader ‘to specify the who, what, where, and when of the allegedly false or fraudulent representation.’” *United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009) (quoting *Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004)). In particular, a complaint must specify “the time, place and content” of the alleged fraud, the connection between that fraud and claims submitted to the government, and the details of particular false claims. *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731 (1st Cir. 2007) (internal quotation marks omitted); *see also Gagne*, 565 F.3d at 44–49; *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232–35 (1st Cir. 2004). Additionally, where a relator does not have first hand knowledge, and instead pleads based on “information and belief,” the complaint must still provide the particular circumstances surrounding the alleged violations, and then must also “set forth the facts on which [the] belief is founded.” *Karvelas*, 360 F.3d at 226 n.8 (citation omitted). These requirements apply equally to the SAC’s state law claims. *See Rost*, 507 F.3d at 731 n.8.

Where a plaintiff alleges that a defendant directly presented a false claim to the government under 31 U.S.C. § 3729(a)(1) (amended 2009),⁴ Rule 9(b) “requires relators to ‘provide details that identify *particular false claims* for payment that were submitted to the

⁴ On May 20, 2009, the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617 (2009), amended certain portions of the FCA. Those amendments do not apply to this case because while the SAC generally alleges conduct through the date of its filing, it only specifically addresses claims submitted between 1993 and 2006.

government.” *Rost*, 507 F.3d at 731 (quoting *Karvelas*, 360 F.3d at 232) (emphasis added); *see also Gagne*, 565 F.3d at 46 (explaining that, for a subsection a(1) claim, complaint must allege details of claims, such as their dates, identification numbers, and amounts). Where a relator brings a claim under § 3729(a)(2), the relator need not describe a particular false claim for payment that was actually submitted directly to the government, but must still allege the particulars of “what the alleged ‘false, misleading and fraudulent pretenses and representations’ consisted of, who made them, [and] when they were made ‘to get a false or fraudulent claim paid or approved by the Government.’” *Gagne*, 565 F.3d at 47 (quoting 31 U.S.C. § 3729(a)(2)).

A. The SAC Alleges No Details About Any Particular “False Claim”

While most, if not all, of Bierman’s allegations appear to be brought under § 3729(a)(1) and analogous state statutes, nowhere does he identify a single, particular claim submitted by Orthofix, Inc. that he can connect to Orthofix, Inc.’s allegedly fraudulent conduct. He does not even attempt to allege any claims submitted—or any pertinent conduct at all—by Orthofix International N.V. While Bierman has filed three exhibits that he contends address this failing, those exhibits still lack details required by Rule 9(b), and fail to connect any particular claim to any allegedly fraudulent scheme: Although Exhibit A contains summary claims data purportedly reflecting sales to Medicare, the exhibit fails to identify any individual claims, the specific dates they were made, the individual amounts submitted, the individuals involved, or what patients were told about renting the device, *see Karvelas*, 360 F.3d at 232–33 (requiring details of individual claims); Exhibit B makes no mention of either Orthofix Defendant at all; and, while the few Orthofix, Inc. entries in Exhibit C purport to reflect individual claims, Bierman makes no effort to connect those entries—or any entries in either of the other two Exhibits—to any of the “fraudulent schemes” he has alleged, *id.* at 232 (stating that pleadings of “[u]nderlying schemes

and other wrongful activities . . . are inadequate unless they are linked to allegations, stated with particularity, of the actual false claims submitted to the government”).

Furthermore, Bierman’s attempt to evade the particularity requirement by alleging that *all* claims billed as purchase items are false also fails. Not only are such attempts to dodge Rule 9(b) rejected in general, as set out in the Joint Memorandum, but this argument is particularly inapplicable to Orthofix. Bierman’s contention that all Orthofix, Inc. claims for purchase were necessarily fraudulent depends on a bare allegation that all Defendants’ BGS could be used for only nine months (SAC ¶ 48 (“[all Defendants’] devices are programmed to deactivate after 9 months”))—a length of use below the threshold at which, according to Bierman, billing for purchase would be legitimate. (*Id.* ¶¶ 33, 113.) However, Bierman’s Orthofix-specific allegations assert that patients could in fact use the Orthofix BGS devices for *longer* than nine months. (*See id.* ¶ 85 (Orthofix representative said that “the units ‘lock up after 12 months’”); *id.* ¶ 90 (Orthofix Regional Vice President said that the “shut-off feature” could be “by-pass[ed]” at one time).) Therefore, based on the SAC itself, patients were not necessarily precluded from using *Orthofix* BGS for more than nine months, and, where there was a need, could in fact have done so.⁵ Because Bierman’s own complaint demonstrates that he has no basis for alleging that *all* Orthofix BGS were used for less than nine months, and were therefore, allegedly, improperly billed as purchases, he must specifically identify which claims for purchase were allegedly improper, and which were not.⁶ He has not done so.

⁵ While Bierman has alleged that typical use of the Devices was “between 3 and 6 months” (SAC ¶ 33), that hardly precludes the existence of patients who used the Devices for ten months or more, and for whom, even under Bierman’s view, billing the devices as a purchase would have been appropriate.

⁶ Perhaps anticipating this issue, Bierman footnotes his allegation that an Orthofix representative told him that the devices would lock up at twelve months with an “*id.*” cite to a prior footnote that simply reiterates his assertion that “E0747” and “E0748” devices shut off after nine months.

Finally, to the extent Bierman has alleged violations of § 3729(a)(2) and analogous state statutes, he similarly fails to plead any particular false statements or representations made by either Orthofix Defendant which were used in connection with any submission of a claim or planned claim to the government. For example, although Bierman alleges generally that “the Defendants” falsified “Certificates of Medical Necessity” (“CMNs”) (SAC ¶¶ 114–15), he does not provide an example of an allegedly false statement made by the Orthofix Defendants in connection with a CMN, nor identify any CMN that the Orthofix Defendants allegedly falsified, nor, critically, connect such a CMN to any of the alleged Orthofix, Inc. claims listed in Exhibit C, or any other actual or planned claim. As explained more fully in the Joint Memorandum, this complete absence of specificity is fatal to any § 3729(a)(2)-based claims Bierman seeks to bring against either Orthofix Defendant.

In sum, Bierman’s failure to allege, with specificity, representative examples of allegedly false claims presented by either Orthofix Defendant, or representative examples of allegedly false and misleading representations made by either Orthofix Defendant to get a false claim paid, requires dismissal of all the FCA and state law counts against both Orthofix Defendants. *Gagne*, 565 F.3d at 47.

B. The SAC Does Not Allege Orthofix International N.V.’s or Orthofix, Inc.’s Involvement in Any Fraudulent Actions with Sufficient Specificity

The SAC not only fails to identify relevant details of particular false claims or statements, but also fails to describe with specificity any involvement by Orthofix, Inc. or Orthofix

Bierman does not, however, allege any basis for this otherwise purely conclusory assertion that the twelve-month shut off allegedly described by an Orthofix representative was an error. Because Bierman alleges no facts to support his conclusion that the representative was mistaken, the Court should disregard the footnote to SAC ¶ 85. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1940–41 (2009) (conclusory assertions should be disregarded when assessing whether a plaintiff has alleged facts that plausibly state all necessary elements of a claim).

International N.V. in the alleged fraudulent schemes. Instead, most of Bierman's allegations that identify facts specific to an Orthofix Defendant merely contain irrelevant, innocuous business information available to basically any consumer that telephones Orthofix, Inc., reads its brochures, or reviews its SEC filings. (*See, e.g.*, SAC ¶ 31 (devices contain automatic deactivation chip); *id.* ¶ 46 (reports publicly filed with FDA explain that stimulators are not "single use" devices); *id.* ¶ 74 (the Orthofix Defendants have a money-back guarantee program); *id.* ¶ 90 (relator was told by an "Orthofix" employee that devices were not available for rental); *id.* Ex. A (report of aggregate annual sales).) None of these allegations can support the theories of fraud that Bierman conclusorily alleges against the Orthofix Defendants; rather, they act only as window-dressing for Bierman's unsupported assertions, which fail to allege with specificity the kinds of facts required to survive the Orthofix Defendants' motion to dismiss.

1. *The SAC's Assertions Regarding an Obligation To Rent and Falsification of Documents Allege No Relevant Facts That Pertain to the Orthofix Defendants*

Once these irrelevant allegations are removed, all that remain are bare allegations with scant Orthofix-Defendant-specific facts, much less facts supported by the "time, manner, and place" details required under Rule 9(b). Bierman's claims regarding the use of CMNs, the use of Forms 1500, and violations of the Supplier Standards contain no links to the Orthofix Defendants beyond Bierman's conclusory assertions. Bierman does not identify the dates of claims or decisions, persons involved, mechanisms used, locations where conduct was committed, or, most importantly, any connection to particular claims filed by an Orthofix Defendant. For instance, he asserts that "the defendants" falsified CMNs (*see* SAC ¶ 125), including by allegedly completing CMN sections that only providers may complete (*see id.* ¶ 114–15). But Bierman fails to allege examples of the Orthofix Defendants engaging in such activity and instead pleads based only on

“information and belief.” As sole support for his “belief” that any defendant falsified CMNs, Bierman cites the fact that two doctors—with no alleged connection to the Orthofix Defendants or Orthofix BGS devices—said they had never seen, or at least never signed, a CMN. (*Id.* ¶ 115, *citing* ¶¶ 79 & 88). These “[c]onclusory allegations . . . are not sufficient.” *Gagne*, 565 F.3d at 45 (citation omitted); *see also Ackerman v. Nw. Mut. Life Ins. Co.*, 172 F.3d 467, 471 (7th Cir. 1999) (“The plaintiffs were required to specify which *defendants* said what to whom and when” (internal quotations omitted)); *Hayduk v. Lanna*, 775 F.2d 441, 444–45 (1st Cir. 1985) (dismissing complaint that attributed actions to “defendants” because it “apprise[d] none of the defendants of the individual charges against them”).

The few Orthofix-Defendant-specific details that Bierman does allege regarding the so-called rental scheme amount to a discussion with sales personnel about Orthofix, Inc.’s rental policies, the secondary market for BGS, and BGS’s “shut-off feature.” (SAC ¶¶ 85, 90.) Once again, while Bierman seeks to allege a fraudulent scheme in general terms, he does not identify the dates of claims or decisions, persons involved, mechanisms used, locations where conduct was committed, or, most importantly, any connection to particular claims filed by the Orthofix Defendants.

2. *The SAC’s Allegations Regarding the Anti-Kickback Statute Fail To Meet the Requirements of Rule 9(b)*

Bierman’s allegations that the Orthofix Defendants violated the Anti-Kickback Statute (the “AKS”), 42 U.S.C. § 1320a-7b(b), by (1) offering free units to physicians, (2) providing volume discounts to suppliers, and (3) paying commissions to sales representatives (SAC ¶ 123) are similarly deficient. Even if these alleged violations formed a proper basis for an FCA claim, Bierman still has failed to plead the who, what, when, where, and how of any fraudulent conduct by either Orthofix Defendant. He has likewise failed to connect any alleged AKS violation to

specific claims on a government payer. Accordingly, Bierman's AKS-based claims fail under Rule 9(b).

Bierman alleges that an unidentified "Orthofix" employee told him that doctors received free units through "buy ten, get one free" deals that were not disclosed on invoices (SAC ¶¶ 102, 123), but does not identify a single physician who received a free unit that was not adequately disclosed—much less a unit that was then improperly billed to Medicare.⁷ Nor does he identify a single referral to the Orthofix Defendants obtained in exchange for offering "buy ten, get one free" deals to physicians, or by providing "compassionate care units" for indigent patients. In short, he offers no specific example of any wrongdoing by either Orthofix Defendant, and makes no effort to connect his general allegations to any particular claim on a federal payer. *See Rost*, 507 F.3d at 732–33 (holding that mere allegations of illegal practices do not meet Rule 9(b) because relator must allege particular facts connecting the conduct to a claim submitted for federal reimbursement).

Bierman also alleges that the Orthofix Defendants provided undisclosed "volume discounts" to suppliers (SAC ¶ 123), but similarly does not identify a single supplier that allegedly received an improperly disclosed discount or any claim that allegedly resulted from such a discount. The complaint's only Orthofix-Defendant-specific allegation addressing volume discounts is that an "Orthofix" employee stated that, aside from the "buy ten, get one free" deals just discussed, "Orthofix" "did *not* have a 'volume discount' program as such." (SAC ¶ 102 (emphasis added).) Given the complete absence of specific factual allegations supporting the theory that Orthofix, Inc. offered improper "volume discounts," and the lack of

⁷ While Bierman alleges that "free units" and "volume discounts" were provided without being invoiced (SAC ¶¶ 102, 123), invoices are not necessary to qualify for statutory and regulatory "safe harbors" from liability for providing free goods. 42 U.S.C. § 1320a–7b(b)(3)(A); 42 C.F.R. § 1001.952(h).

any allegation that Orthofix International N.V. had any role whatsoever in offering free units or providing volume discounts, Rule 9(b) compels dismissal of the discount-based claims against both Orthofix, Inc. and Orthofix International N.V.

Finally, Bierman alleges that the Orthofix Defendants paid commissions to independent sales representatives. (SAC ¶¶ 101, 123.) Yet Bierman makes no attempt to explain how the mere use of independent sales representatives violates the AKS,⁸ much less to identify the time, manner, and place of any illegal use of independent sales representatives. *See Gagne*, 565 F.3d at 47 (holding that complaint failed to meet Rule 9(b) where, among other problems, it failed to identify laws violated or explain why actions were fraudulent). Nor does Bierman identify any claims submitted to the government as a result of such allegedly illicit arrangements. Once again, he makes no effort to tie the few claims listed in Exhibit C—the only Orthofix, Inc. claims he attempts to identify—to any alleged misconduct. Because the SAC offers no particularized factual allegations of illegal activity and resulting claims on Medicare by Orthofix, Inc., and no allegations of any pertinent conduct by Orthofix International N.V., Bierman’s AKS-based claims against both Orthofix Defendants must be dismissed.

II. BIERMAN’S SAC SHOULD BE DISMISSED WITH PREJUDICE

For the reasons set out in the Joint Memorandum, Bierman’s SAC should be dismissed with prejudice as to Orthofix, Inc. and Orthofix International N.V..

CONCLUSION

For all of the foregoing reasons, the Orthofix Defendants request that the Court grant this motion to dismiss, with prejudice, and dismiss Bierman’s SAC in its entirety.

⁸ Indeed, the “personal services” safe harbor protects payments for services provided by individuals or entities. *See* 42 § U.S.C. 1320a–7b(b)(3); 42 C.F.R. § 1001.952(d).

Dated: August 17, 2010

Respectfully submitted,

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CERTIFICATE OF CONFERENCE

Pursuant to Local Rule 7.1, I hereby certify that counsel for the Defendants has conferred with Relator's counsel in a good faith attempt to resolve or narrow the issues presented by this motion.

Dated: August 17, 2010

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CERTIFICATE OF SERVICE

I hereby certify that these documents filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non registered participants on August 17, 2010.

Dated: August 17, 2010

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